REMARKS

The Amendments

The specification is amended to correct an inadvertent error in reciting the effective filing date of the provisional application to which this application claims benefit.

Additional claims are added. The amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability.

The Rejection under 35 U.S.C. § 103

The rejection of claims 90-96, 98-119, 122, 134 and 138-152 under 35 U.S.C. § 103, as being obvious over Elliesen (WO 97/11680) in view of Backenfeld (US Publication No. 2002/0173487) or over Backenfeld in view of Elliesen, is respectfully traversed.

Backenfeld is not prior art. The reference was published in 2002, well after applicants' filing date. Backenfeld was filed on December 20, 2001, and claims benefit of a U.S. Provisional application filed December 20, 2000. Thus, its earliest possible 35 U.S.C. § 102(e) date is December 20, 2000.

The instant application claims the benefit of U.S. Provisional 60/325,760 filed January 18, 2000. The incorrect date had been stated in the benefit claim added to the beginning of the specification and this has been corrected by the above amendment. The undersigned apologize for the confusion. The history of the provisional application is complicated by the fact that it was originally filed on January 18, 2000, as a non-provisional application and then converted to a provisional application on January 11, 2001. But the correct priority date is January 18, 2000. This date obviously pre-dates the December 20, 2000, 35 U.S.C. § 102(e) date of Backenfeld.

In any event, Backenfeld and the instant application are commonly owned; both are assigned of record to Schering Aktiengesellschaft. Moreover, the inventions of each application have always been commonly owned by Schering. 35 U.S.C. § 103(c) prohibits

applying 35 U.S.C. § 102(e), (f) or (g) in combination with 35 U.S.C. § 103 under such circumstances.

Since both forms of the rejections, i.e., Elliesen in view of Backenfeld or Backenfeld in view of Elliesen, require the Backenfeld reference, the rejections as a whole must be withdrawn.

The Examiner's Remarks on the Declarations of Drs. Lipp and Elliesen

The characterization of Dr. Lipp's declaration in the "Response to Remarks" on pages 4-5 of the Office Action requires correction. The Office Action states that:

> According to the explanation of Dr. Lipp, isomerization of DRSP to an inactive form occurs in the intestine due to the acidic pH conditions and that applicants showed that micronization hastens the isomerization to an inactive form.

And further:

> applicants state that if providing DRSP in a micronized form could have been expected to increase its surface area and exposure to environment (an argument presented in the last Office Action), such a process would have caused inactivation of the compound.

It is concluded in the Office Action that:

> the arguments were not found persuasive because if it is known that micronized DRSP results in an active [sp: inactive] form, how is it possible that a micronized DRSP in the instant claim is effective in providing HRT and in providing claimed unexpected result of Figure 3 (instant application).

Dr. Lipp's declaration has been misread. Dr. Lipp stated "if providing drospirenone for oral administration in micronized form could have been expected to increase its surface area and thus exposure to its environment, as suggested by the Examiner in the Office Action, such increased exposure would have been expected by one of ordinary skill in the art to expose more of the drospirenone to rapid isomerization to its inactive form in the stomach." Dr. Lipp's statements are not contradictory of the claimed invention. Rather, they show why one of ordinary skill in the art was not motivated towards applicants' invention.

The Provisional Obviousness-type Double Patenting Rejection

The order of issuance of the relevant claim sets should be known before determining the appropriate action. When one of the claim sets is in position for patenting except for this issue, applicants will address the merits, as appropriate. It is noted that this is only a provisional rejection. However, the copending application contains only composition and kit claims -- no claims to methods such as those claimed here. Under *General Foods Corp. v. Studiengessellschaft KohleGmbH*, 972 F.2d 1272, 23 USPQ 2d 1839 (Fed. Cir.1992), the latter claims are not rejectable for obviousness-type double patenting over the former.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

John A. Sopp, Reg. No. 33,103

Anthony J. Zelano, Reg. No. 27,969

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: PLOVIN-2A

Date: November 30, 2003

K:\Plovin\2a\Reply to 5-30-03 OA.doc